UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS LLC, AND ACTAVIS PHARMA, INC.'S MOTION FOR SUMMARY JUDGMENT[1]

[1] This Motion for Summary Judgment concerns the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"), specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC ("MSP"), as class representative of TPP Breach of Express Warranty subclass b, TPP Breach of Implied Warranty subclass d, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a (collectively, the "TPP Classes"), against the TPP Trial Defendants, including Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc. (collectively, "Teva" or the "Teva Defendants"). Doc. 2343, at 1-2. Accordingly, this motion is limited to the TPP Trial Claims, and is presented without waiver of any arguments for summary judgment with respect to any other claims asserted by any Plaintiff as to any Defendant in this multi-district litigation.

INTRODUCTION

Teva moves for summary judgment on all of the TPP Trial Claims asserted against the four Teva Defendants. In addition to the grounds set forth in the TPP Trial Defendants' Omnibus Motion for Summary Judgment (the "Omnibus Motion"),[2] filed contemporaneously with this motion and incorporated herein by reference, the Teva Defendants are further entitled to summary judgment on four Teva-specific grounds: (1) the Court lacks personal jurisdiction over Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") with respect to the TPP Trial Claims; (2) Teva's VCDs were not adulterated as a matter of law; (3) Plaintiffs have failed to present any evidence that Teva acted with the requisite scienter with respect to Plaintiffs' fraud claims; and (4) Plaintiffs have failed to present any evidence supporting recovery of punitive or exemplary damages against Teva.

For each of these reasons, the Court should grant summary judgment against Plaintiffs and in favor of Teva on each claim.

FACTUAL BACKGROUND

The facts relevant to this motion are set forth in detail in the SUMF, which is incorporated herein, with certain undisputed Teva-specific facts summarized below.

[2] Capitalized terms have the same meaning here as in the Omnibus Motion and the accompanying TPP Trial Defendants' Statement of Material Facts Not in Dispute ("SUMF") and exhibits.

Teva Ltd. is an Israeli corporation headquartered in Israel. (SUMF ¶ 4.) The TPP Trial Claims against Teva relate to valsartan finished dose product manufactured using ZHP's API. (*Id.*) Teva Ltd. did not manufacture, sell, or ship any of the VCDs at issue in the TPP Trial Claims. (*Id.*) These functions were at all times handled by the other Teva Defendants. (*Id.*)

Teva (excluding Teva Ltd.) manufactured approximately 36 finished-dose VCDs using ZHP's API that were included in a voluntary recall due to the detection of NDMA. (*Id*. ¶ 4.) Teva first learned of the previously unknown NDMA impurity in ZHP's API when ZHP informed it of the issue on June 20, 2018. (*Id*. ¶ 39.) Neither Teva's testing nor audits of ZHP provided evidence to suggest NDMA would be present in the API. (*Id*. ¶ 40.) Upon learning of the impurity, Teva initiated a voluntary recall of its corresponding VCDs on July 16, 2018. (*Id*. ¶ 41.)

Teva's manufacturing facilities received acceptable Current Good Manufacturing Practices ("cGMP") inspections from all regulators during the relevant time period, with no issues to which the presence of nitrosamine impurities may be attributed. (*Id*. ¶ 18.). The U.S. Food & Drug Administration ("FDA") never issued any Warning Letters or put any hold on VCDs manufactured in Teva's facilities for nitrosamine impurities, and did not send any communications to Teva that products sold under its Abbreviated New Drug Applications ("ANDAs") were no longer AB-rated to their corresponding reference listed drugs ("RLDs"). (*Id*. ¶¶

18, 97.) The FDA did not find or declare any VCDs or API used to manufacture VCDs "adulterated" until, at the earliest, November 29, 2018, by which time all of Teva's medications containing the affected ZHP API had been voluntarily recalled. (*Id.* ¶ 96.) The FDA never found Teva's VCDs adulterated at any time, before or after Teva's recall of the VCDs. (*Id.* ¶¶ 18, 100.)

There were no interim acceptable limits for levels of nitrosamines in finished-dose products prior to December 2018, and Teva complied with all pre-December 2018 guidelines and compendial and approved ANDA specifications, with labeling that conformed to the RLDs. (*Id*. ¶¶ 18-21, 67-76, 96-100.) At no time did Teva sell adulterated VCDs. (*Id.* ¶¶ 96-100.)

ARGUMENT

I. THE COURT LACKS PERSONAL JURISDICTION OVER TEVA LTD. WITH RESPECT TO THE TPP TRIAL CLAIMS.

The TPP Trial Claims relate exclusively to VCDs manufactured using ZHP's API. (SUMF ¶ 4.) Only three of the named Teva entities, Actavis LLC, Actavis Pharma, Inc., and Teva Pharmaceuticals USA, Inc., manufactured, sold, or distributed these products to or in the United States. (*Id.* ¶ 4.) Teva Ltd., an Israeli corporation, did not manufacture, sell, or distribute these products. (*Id*. ¶ 4.) Its sole relationship to the TPP Trial Claims is as an indirect parent corporation.

Based on these undisputed facts, Teva Ltd. is not "at home" in any United States jurisdiction and thus is not subject to general jurisdiction. *Daimler AG v.*

Bauman, 571 U.S. 117, 137 (2014). It also is not subject to specific personal jurisdiction in relation to any of the TPP Trial Claims, because the claims do not "arise out of or relate to" any activities "purposefully directed" by Teva Ltd. at the District of New Jersey or any United States jurisdiction. *Burger King v. Rudzewicz*, 471 U.S. 462, 476 (1985); *see also Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1780 (2017).

Being the foreign parent of a local subsidiary "without more, is insufficient to confer personal jurisdiction" over a nonresident defendant. *Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 156 (3d Cir. 2010) (applying Delaware long-arm statute, which is coextensive with the limits of constitutional due process); *see also Lucas v. Gulf & W. Indus., Inc.*, 666 F.2d 800, 805-06 (3d Cir. 1981) (quoting 2 *Moore's Federal Practice* § 4.25(6) (1981) (similar). Contracting with a resident domestic distributor also is not sufficient to establish jurisdiction over the contracting party. *Bristol-Myers*, 137 S. Ct. at 1783. The Court thus lacks personal jurisdiction over Teva Ltd. with respect to the TPP Trial Claims.

II. TEVA'S VCDs WERE NOT ADULTERATED.

Teva's VCDs were never deemed or found adulterated by the FDA, the sole regulatory agency with statutory authority to make such a determination. (SUMF ¶¶ 18, 100.) Teva complied with all pre-December 2018 guidelines, standards, and specifications applicable to the at-issue VCDs. (*Id.* ¶¶ 18-21, 67-76, 96-100.) It never

sold adulterated VCDs. (*Id.* ¶¶ 96-100.). The FDA did not find any API used to manufacture VCDs "adulterated" until November 29, 2018, by which time all of Teva's VCDs containing the affected ZHP API had been voluntarily recalled. (*Id.* ¶ 96). And the FDA never found Teva's VCDs adulterated at any time, before or after Teva's voluntary recall of the VCDs. (*Id.* ¶¶ 18, 100.) Accordingly, the Court should enter judgment in Teva's favor with respect to all of Plaintiffs' claims against Teva, because every claim is predicated on the unsupportable theory that Teva sold "adulterated" API. (*See, e.g.,* Compl. ¶¶ 2, 4, 7, 9, 12, 99-102, 209-24, 240-41, 384-402, 404-08, 409-10, 413, 419, 422-23, 597-98, 601, 614, 623-24, 628-30, 641, 660, 678, 691-94, 708-09, 711, 727-28, 730-32, 737.)

Adulteration is statutorily defined in the Federal Food, Drug, and Cosmetic Act ("FDCA") and requires satisfaction of specific criteria. *See* 21 U.S.C. § 351(a)(2)(B) (defining "adulterated"). "The FDA—and the FDA alone—has the power and the discretion to enforce the FDCA." *Allergan, Inc. v. Athena Cosms., Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013); *see also* 21 U.S.C. § 337(a) (vesting exclusive enforcement authority in the United States). Consistent with these principles, "[c]laims of adulteration should be resolved by the FDA." *Healthpoint, Ltd. v. Stratus Pharmaceuticals, Inc.*, 273 F. Supp. 2d 769 (W.D. Tex. 2001) (declining to consider claims for injunctive relief "based on claims or arguments that [defendant] incorrectly labeled or misbranded" its product or "based on the argument

that [defendant's] alleged low or varying level of papain render it adulterated"). It is undisputed, and Plaintiffs' experts admit, that the FDA never determined Teva's VCDs were adulterated. (SUMF ¶¶ 18, 100.). That is dispositive of the matter.[3] The record establishes that Teva's VCDs were not adulterated, and because all of the TPP Trial Claims are predicated on the allegation that Teva's VCDs were adulterated, they all fail as a matter of law.

III. PLAINTIFFS' FRAUD CLAIMS FAIL BECAUSE THERE IS NO EVIDENCE TEVA ACTED WITH THE REQUISITE SCIENTER.

Teva is separately entitled to summary judgment on Plaintiffs' fraud claims because Plaintiffs cannot prove it acted with the requisite level of scienter. As this Court previously recognized, to prevail on their common-law fraud claims, Plaintiffs must prove at a minimum that Teva did so with knowledge of the alleged falsity. (*See* Doc. 2261, at 32; Doc. 2261-3 at H-3, H-13, H-18 to H-19, H-22, H-29, H-31,

[3] Several of Plaintiffs' experts made improper attempts at deposition to opine that at-issue VCDs were adulterated. Nearly all of these experts, however, offered no adulteration opinions as to Teva in their expert reports and none should be permitted to opine as to whether Teva's product was adulterated, as set forth in Defendants' pending Rule 702 motions. (*See* Doc. Nos. 2284, 2285, 2287 & 2292.) Indeed, the only expert to assess Teva's conduct in any detail, Philip Russ, specifically admitted at his deposition that he would not be offering any opinions as to whether Teva's VCDs were adulterated. (SUMF ¶ 100.) Regardless, these opinions cannot create an issue of material fact as to whether Teva's VCDs were adulterated—a legal determination left solely to the FDA. *See Robinson v. Ethicon, Inc.*, No. CVH-20-03760, 2022 WL 614919, at *6 (S.D. Tex. Mar. 2, 2022) (holding that expert "cannot take the final step of opining that the product was 'misbranded' or 'adulterated,' as these are impermissible legal conclusions").

H-33, H-40 to H-54.) Indeed, several of the jurisdictions at issue (Iowa, Louisiana, North Carolina, Ohio, South Dakota, Virginia, and D.C.) require a higher degree of scienter, *i.e.*, a specific intent to deceive or mislead. (*See* Doc. 2261-3, at 32, H-3, H-13, H-18, H-19, H-22, H-29, H-31, H-33, H-40 to H-54.)[4]

Here, the record establishes as an undisputed fact that Teva had no knowledge of the existence of an NDMA impurity in the API it purchased from ZHP until ZHP first informed Teva of the issue on June 20, 2018. (SUMF ¶ 39.) Prior to that date, Teva had tested ZHP's API and audited ZHP's facilities, and neither had provided evidence to suggest the presence of NDMA in the API. (*Id.* ¶ 40.) Plaintiffs have presented no evidence that Teva was aware of the 2017 email from ZHP employee Jinsheng Lin on which Plaintiffs rely in an unsuccessful attempt to impute scienter to ZHP—but not to Teva. Plaintiffs thus cannot prove that Teva had any knowledge whatsoever of the presence of NDMA in ZHP's API. Nor have Plaintiffs presented

[4] *See also, e.g., Kitt v. Cap. Concerts, Inc.*, 742 A.2d 856, 860 (D.C. 1999) ("The essential elements of common law fraud" include "the intent to deceive") (D.C. law); *Seibert v. Noble*, 499 N.W.2d 3, 7 (Iowa 1993) ("Among the elements of fraud is an intent to deceive, which the other party relies upon with resulting damages to the relying party.") (Iowa law); *Chateau Homes by RJM, Inc. v. Aucoin*, 11-1118 (La. App. 5 Cir. 5/31/12), 97 So. 3d 398, 404, *writ denied*, 2012-1526 (La. 10/12/12), 98 So. 3d 872 ("For purposes of the tort of fraud, the intent to deceive is a specific intent.") (Louisiana law); *Forbis v. Neal,* 361 N.C. 519, 526–27 (2007) (actual fraud requires an "intent to deceive") (North Carolina law); *Est. of Johnson ex rel. Johnson v. Weber*, 898 N.W.2d 718, 729 (S.D. 2017) (fraud requires proof the defendant "made the representation with intent to deceive") (South Dakota); *Owens v. DRS Auto. Fantomworks, Inc.*, 288 Va. 489, 497 (2014) (common law fraud requires "intent to mislead") (Virginia law).

any evidence from which a jury could infer Teva's intent to deceive or mislead in the seven jurisdictions requiring this enhanced level of scienter.

Accordingly, Teva is entitled to summary judgment in its favor on all of Plaintiffs' common-law fraud claims against Teva. *See In re TMJ Implants Prod. Liab. Litig.*, 880 F. Supp. 1311, 1317 (D. Minn. 1995), *aff'd sub nom. In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 113 F.3d 1484 (8th Cir. 1997) (granting summary judgment on fraudulent misrepresentation and omission claims regarding safety of silicone breast implants because plaintiff offered no evidence of defendant's knowledge of the danger); *Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231 (S.D.N.Y. 2022) (holding that allegations that defendant "may have known that its medication was at risk of [nitrosamine] contamination by late 2020" was insufficient to "show that [the defendant] knew or believed that [the drug] was actually contaminated") (emphasis in original).

IV. PLAINTIFFS CANNOT RECOVER PUNITIVE DAMAGES AGAINST TEVA.

Just as Plaintiffs cannot prove scienter against Teva, so too they cannot recover punitive damages against Teva because they have failed to present any evidence that Teva acted with the requisite culpability to support a punitive damages award. Plaintiffs cannot recover punitive damages as to any of the TPP Defendants (*see* Omnibus Motion, Argument § IV.C), but Plaintiffs' case for punitive damages is particularly lacking with respect to Teva.

Absent evidence that Teva even knew of the NDMA impurity, *see* § III, *supra*, Plaintiffs cannot demonstrate willful, malicious, or egregious misconduct, as required to recover punitive damages in the handful of states allowing recovery of punitive damages for breach of warranty. *See, e.g., Hughes v. Segal Enterprises*, Inc., 627 F. Supp. 1231, 1238 (W.D. Ark. 1986); *see also* Omnibus Motion, Argument § IV.C. Nor can Plaintiffs satisfy the exacting state-of-mind or culpability standards required to recover punitive damages for fraud or under state consumer protection statutes. *See, e.g., Johnston v. Vincent*, 359 So.3d 896, 919 (La. 2023); *Princes Point, LLC v. AKRF Eng'g, P.C.*, 94 A.D.3d 588, 589 (1st Dep't 2012); *K. Ronald Bailey Assoc. Co. v. Soltesz*, 2006 Ohio 2489, ¶ 19 (Ohio Ct. App. 2006); *Holeman v. Neils*, 803 F. Supp. 237, 242-43 (D. Ariz. 1992); *see also* Omnibus Motion § IV.C. Accordingly, Teva is entitled to summary judgment with respect to Plaintiffs' claims of punitive damages against Teva.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of Teva on all of Plaintiffs' claims.

Dated: December 22, 2023

Respectfully submitted,

By: */s/ Gregory E. Ostfeld*

Gregory E. Ostfeld
GREENBERG TRAURIG, LLP
Tiffany M. Andras
77 West Wacker Drive, Suite 3100
Chicago, Illinois 60601

Tel: (312) 456-8400
ostfeldg@gtlaw.com
andrast@gtlaw.com

Lori G. Cohen
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Rd., NE, Suite 2500
Atlanta, Georgia 30305
Tel: (678) 553-2385
Fax: (678) 553-2386
cohenl@gtlaw.com
lockardv@gtlaw.com
harkinss@gtlaw.com

Attorneys for Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 22, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Gerond J. Lawrence
Gerond J. Lawrence,
Greenberg Traurig, LLP